May 27, 2005

Anne P. LeHuray, Ph.D.
American Chemistry Council
Specialty Acrylates & Methacrylates Panel
1300 Wilson Boulevard
Arlington, VA 22209

Dear Dr. LeHuray:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Isodecyl 2-propenoate (isodecyl acrylate) posted on the ChemRTK HPV Challenge Program Web site on March 5, 2004. I commend the American Chemistry Council Specialty Acrylates & Methacrylates Panel for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: M. E. Weber
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Isodecyl 2-Propenoate

Summary of EPA Comments

The sponsor, the American Chemistry Council Specialty Acrylates & Methacrylates Panel, submitted a test plan and robust summaries to EPA for isodecyl 2-propenoate (isodecyl acrylate, IDA; CAS No.1330-61-6) dated December 24, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on March 5, 2004. Information was also provided for the analog isooctyl 2-propenoate (isooctyl acrylate, IOA; CAS No. 29590-42-9).

EPA has reviewed this submission and has reached the following conclusions:

1. Analog Justification. EPA agrees that isooctyl acrylate is a reasonable analog for the health effects and ecological effects endpoints for the purposes of the HPV Challenge Program.

2. Physicochemical Properties. The submitter needs to provide measured vapor pressure and water solubility data for isodecyl acrylate.

3. Environmental Fate. The submitter needs to recalculate its fugacity model using measured vapor pressure and water solubility values.

4. Health Effects. The submitted analog data are adequate for the acute toxicity, repeated-dose toxicity. reproductive toxicity and developmental toxicity endpoints for the purposes of the HPV Challenge Program. Testing is needed to address the chromosomal aberrations endpoint. The submitter needs to address deficiencies in the robust summaries.

5. Ecological Effects. EPA reserves judgement on the submitted analog data for the fish, invertebrate, and algae toxicity endpoints pending receipt from the submitter of enhanced robust summaries.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the Isodecyl 2-propenoate Challenge Submission

Analog Justification

EPA agrees that isooctyl acrylate (IOA) is a reasonable analog for the health effects and ecological effects endpoints for the purposes of the HPV Challenge Program. However, if there are additional supporting comparative toxicologic data or information on metabolism the submitter needs to provide it.

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data provided by the submitter for melting point, boiling point, and partition coefficient are adequate for the purposes of the HPV Challenge Program.

Vapor pressure. The vapor pressure data provided by the submitter are not adequate for the purposes of the HPV Challenge Program. The submitter's estimated and analog values (for IOA) are not adequate for the purposes of the HPV Challenge Program. Analog values, and estimated values above 10^{-5} Pa (7.5×10^{-8} mm Hg) are not acceptable because the use of estimated or calculated values, or of analog

data, introduces uncertainties that then become magnified in modeling applications. The submitter needs to provide measured vapor pressure data for IDA following OECD TG 104.

Water solubility. The water solubility data provided by the submitter are not adequate for the purposes of the HPV Challenge Program. The submitter's estimated and analog values (for IOA) are not adequate for the purposes of the HPV Challenge Program. Analog values, and estimated values above above 1 ug/L are not acceptable because the use of estimated or calculated values, or of analog data, introduces uncertainties that then become magnified in modeling applications. For purposes of the HPV Challenge Program, the submitter needs to provide measured water solubility data for IDA following OECD TG 105.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for photodegradation, stability in water, and biodegradation are adequate for the purposes of the HPV Challenge Program.

Fugacity. The submitter needs to recalculate the fugacity values using measured vapor pressure and water solubility values for IDA in the model. As already stated above, the use of estimated or analog physicochemical data introduces uncertainties that then become magnified in modeling applications.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

The submitted analog data are adequate for the acute, repeated-dose, reproductive, and developmental toxicity endpoints for the purposes of the HPV Challenge Program. The submitter needs to address deficiencies in the robust summaries.

Genetic toxicity - chromosomal aberrations. A robust summary was not submitted on either the analog or IDA for a chromosomal aberrations assay. *In vitro* testing is needed for the chromosomal aberrations endpoint following OECD TG 473.

Ecological Effects (fish, invertebrates, and algae)

EPA reserves judgement on these endpoints The robust summaries for the unpublished data on the analog, IOA, need to be sufficiently enhanced so that an independent evaluation can be made. See EPA's HPV Challenge Program Guidance on robust summary preparation at http://www.epa.gov/opptirtr/chemrtk/guidocs.htm.

Specific Comments on the Robust Summaries

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Acute toxicity. The submitter needs to state the test substance purity of the analog in the robust summary.

Repeated-dose toxicity. The submitter needs to report the number of animals/sex/concentration for the repeated-dose study on the analog. The submitter needs to explain any deviations from OECD TG 422 in the methods section including the lack of hematological and clinical chemistry testing in female animals and the absence of functional observations for neurotoxicity (mild central nervous system depression was observed in the acute oral toxicity test).

Genetic toxicity - gene mutations. The robust summaries on the analog data for the gene mutation assay in *Salmonella typhimurium* and for the mouse lymphoma cell assay are both missing details including culture conditions. An attempt should be made to locate information on the purity of the test substance.

Reproductive and developmental toxicity. The robust summary for the combined repeated-dose, reproductive and developmental toxicity study on the analog is missing details including the number of animals/sex/concentration, and the number of pregnant females per group.

Ecological Effects (fish, invertebrates, and algae)

All of the robust summaries for the unpublished acute and chronic aquatic studies on the analog lack sufficient method details, including information on pH, DO content, water hardness, water temperature, quantity of solvent used if any, percent purity of the test substance, measured/nominal concentrations, and TOC. Log Kow input values need to be included in the SAR robust summaries.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.